

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  00201-WO11	<b>FOR FURTHER ACTION</b>  see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No.  PCT/DK2004/000574	International filing date (day/month/year)  30/08/2004	(Earliest) Priority Date (day/month/year)  29/08/2003
Applicant  LIFECYCLE PHARMA A/S		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**SOLID DISPERSIONS COMPRISING TACROLIMUS**

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/DK2004/000574

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/436 A61K9/16 A61K9/14 A61P37/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, MEDLINE, BIOSIS, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/37808 A (LIPOCINE INC) 31 May 2001 (2001-05-31)  example 20; claim 1, 5	1-10, 15, 19-24, 26-31, 33, 36, 37, 42-49, 51
X	EP 1 064 942 A (FUJISAWA PHARMACEUTICAL CO) 3 January 2001 (2001-01-03)  '0002!-'0004!; example 12, 27, 29 ----- -/--	1-10, 12, 15, 19-31, 33, 36-38, 42-49, 51

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

8 November 2004

Date of mailing of the international search report

30/11/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Borst, M

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK2004/000574

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HONBO T ET AL: "The oral dosage form of FK-506" TRANSPLANTATION PROCEEDINGS 1987 UNITED STATES, vol. 19, no. 5 SUPPL. 6, 1987, pages 17-22, XP0009024313 ISSN: 0041-1345 page 17, paragraph entitled "Preparation of the Oral dosage Form"	1-5, 7-10, 12, 45-49, 51
Y	page 21-22, paragraph entitled "Discussion"	1-51
Y	----- WO 03/004001 A (HOLM JANNIE EGESKOV ; MOELLGAARD BIRGITTE (DK); BUUR ANDERS (DK); HOLM) 16 January 2003 (2003-01-16) cited in the application page 11, line 30 - page 12, line 16; table 2; example 4, 6 -----	1-51
A	SANO N ET AL: "Oral FK 506 blood levels are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor." TRANSPLANTATION PROCEEDINGS, vol. 34, no. 3, May 2002 (2002-05), pages 1050-1051, XP002304068 ISSN: 0041-1345 page 1051, paragraph entitled "Discussion"	1-51
P,A	----- NISHI K ET AL: "The expression of intestinal CYP3A4 in the piglet model." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 361-363, XP002304069 ISSN: 0041-1345 page 363, paragraph entitled "Discussion"	1-51
P,A	----- NISHI K ET AL: "The colon displays an absorptive capacity of tacrolimus." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 364-366, XP002304070 ISSN: 0041-1345 page 365-366, paragraph entitled "Discussion" -----	1-51

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2004/000574

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 0137808	A	31-05-2001	US	6248363 B1		19-06-2001
			AU	1798101 A		04-06-2001
			CA	2391923 A1		31-05-2001
			EP	1233756 A1		28-08-2002
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EP 1064942	A	03-01-2001	AT	269075 T		15-07-2004
			AU	749623 B2		27-06-2002
			AU	2856399 A		18-10-1999
			BR	9909201 A		14-11-2000
			CA	2322516 A1		07-10-1999
			DE	69918074 D1		22-07-2004
			DE	69918074 T2		04-11-2004
			EP	1064942 A1		03-01-2001
			HR	20000707 A1		31-12-2001
			HU	0101237 A2		28-09-2001
			NO	20004773 A		23-11-2000
			NZ	507211 A		25-07-2003
			RU	2214244 C2		20-10-2003
			SK	14392000 A3		12-03-2001
			US	6440458 B1		27-08-2002
			CN	1301157 T		27-06-2001
			EP	1421939 A1		26-05-2004
			ID	27825 A		26-04-2001
			WO	9949863 A1		07-10-1999
			PL	343096 A1		30-07-2001
			TR	200002771 T2		21-02-2001
			TW	570814 B		11-01-2004
			US	2003235614 A1		25-12-2003
			US	2002044967 A1		18-04-2002
			ZA	200004963 A		08-01-2002
WO 03004001	A	16-01-2003	BR	0210867 A		29-06-2004
			CA	2452330 A1		16-01-2003
			WO	03004001 A1		16-01-2003
			EP	1406594 A1		14-04-2004

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

**To:**

see form PCT/ISA/220

# PCT

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43*bis*.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/DK2004/000574

International filing date (day/month/year)  
30.08.2004

Priority date (day/month/year)  
29.08.2003

International Patent Classification (IPC) or both national classification and IPC  
A61K31/436, A61K9/16, A61K9/14, A61P37/06

**Applicant**  
**LIFECYCLE PHARMA AS**

1. This opinion contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I   | Basis of the opinion  |
| <input checked="" type="checkbox"/> Box No. II  | Priority  |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV             | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V   | Reasoned statement under Rule 43b/s.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI             | Certain documents cited   |
| <input type="checkbox"/> Box No. VII            | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII           | Certain observations on the international application   |

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCTISA/Z20 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

- 3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA:



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

**Authorized Officer**

**Borst, M**

**Telephone No. +49 89 2398-8648**

